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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/603,705 | 06/25/2003 | Kent Harrison | 10527-454001 | 3440 |

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BOSTON, MA 02110

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| EXAMINER |
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JOHNSON III, HENRY M

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| ART UNIT | PAPER NUMBER |
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3739

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,705

Applicant(s)

HARRISON, KENT

Examiner

Henry M Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-18, 23, 24, 35, 36, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 19-22, 25-34 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-18, 23, 24, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 38 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1 as shown by embodiment 1 in Figures 1-4.

Species 2 as shown by embodiment 2 in Figures 6-8.

Species 3 as shown by embodiment 3 in Figure 9.

Species 4 as shown by embodiment 4 in Figures 10 and 11.

Species 5 as shown by embodiment 5 in Figures 12A and 12B.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

During a telephone conversation with Kent Harrison on December 20, 2005 a provisional election was made with traverse to prosecute the invention of species 1, claims 1-4, 7-9, 10-24, 35-36, 38 and 39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-22 relate to species 3 and 5 and are therefore not considered. Claims 5, 6, 19-22, 25-34 and 37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

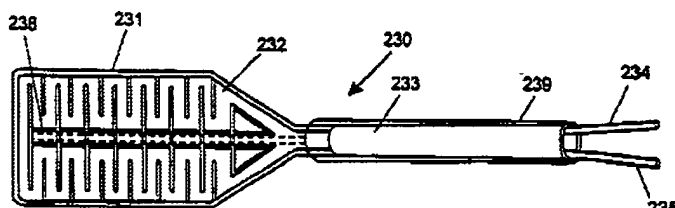
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-17 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,799,661 to Boyd et al. Boyd et al. teach devices and methods for cardiac surgery including a device for cooling tissue comprising an elongate shaft (Fig. 42, # 233) with a deployable cooling structure at its distal end (Fig. 42, # 231), delivered to the treatment site via a sheath (Fig. 42, # 239). The flexible heat exchanger (231) is collapsible to a pre-deployed



position which can easily fit through an access port into the chest of the patient. The flexible heat exchanger is attached to the distal end of an elongated tubular

shaft (233). An inflow lumen (234) extends through the tubular shaft and is fluidly connected to the flexible heat exchanger. A return lumen (235) extends through the tubular shaft parallel to the inflow lumen. The lumens may be formed integrally with the tubular shaft. The proximal ends of the inflow lumen and the return lumen are adapted for attachment to a circulating pump and a reservoir of cooling fluid (Col. 21, lines 5-25). The flexible heat exchanger is interpreted as a patch and the shaft is longitudinally movable with the sheath. The flexible heat exchanger is made from two sheets of flexible plastic which are heat sealed or RF sealed together to form a serpentine cooling path (232) through the heat exchanger. Preferred materials for manufacturing the flexible heat exchanger 231 include polyurethane, vinyl, polypropylene,

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nylon, etc. The flexible heat exchanger may have a flexible backbone (frame) which extends from the distal end of the tubular shaft to the distal edge of the heat exchanger. The flexible backbone may be made from a flexible polymer, elastomer, or a resilient metal wire, such as spring temper stainless steel or a superelastic nickel/titanium alloy, or a composite of metal and plastic. The flexible heat exchanger is rolled, folded or twisted and placed in an introducer sheath 239 in the pre-deployed position (Col. 21, lines 25-41).

Regarding claim 14, the limitation is intended use with no structure modifications.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,799,661 to Boyd et al. Boyd et al. disclose the claimed invention except for dual patches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an additional patch, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,799,661 to Boyd et al. in view of U.S. Patent 6,514,245 to Williams et al. Boyd et al. are discussed above, but do not teach the use of gas expansion or the Joule-Thompson effect for cooling. Williams et al. disclose a cryotherapy catheter where the cooling fluid may pass through a Joule-Thompson orifice between fluid supply lumen and balloon (Col. 14, lines 44-48). It would have been obvious to one having ordinary skill in the art at the time the invention was

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made to use the Joule-Thompson cooling as disclosed by Williams et al. in the device of Boyd et al. because it is a well known methodology for cooling medical devices.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,799,661 to Boyd et al. in view of U.S. Patent Application Publication US 2004.0030259 to Dae et al. Boyd et al. are discussed above, but do not teach a temperature sensor near the heat exchange area. Temperature sensors are well known and pervasive in the art as evidenced by the sensor of Dae et al. (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a temperature sensor as taught by Dae et al. in the device of Boyd et al. to monitor the process of cooling.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,799,661 to Boyd et al. in view of U.S. Patent 5,837,003 to Ginsburg. Boyd et al. are discussed above and disclose using a deployable pad to cool tissue, but do not specifically disclose a method of use within a blood vessel. Ginsburg teaches a catheter for cooling a body and a method for positioning the catheter within a blood vessel and deploying a balloon (fig. 7, # 70) to cool tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the deployable patch as taught by Boyd et al. within a blood vessel as taught by Ginsburg as the patch is designed for delivery via a small diameter cannula and would provide increased surface area for cooling.

Allowable Subject Matter

Claims 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

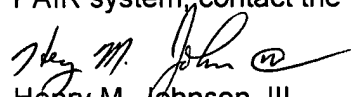
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Patent Examiner
Art Unit 3739